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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,277	10/31/2003	Bryn Hird	8473MR2	2057

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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09/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/699,277	Applicant(s) HIRD ET AL.	
	Examiner KEVIN WEDDINGTON	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,8,9,23,25-27 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,8,9,23,25-27 and 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1, 6, 8, 9, 23, 25-27 and 29-38 are presented for examination.

Applicants' request for continued examination, amendment and response filed August 25, 2010 have been received and entered.

Accordingly, the rejection made under 35 USC 112, first paragraph (Scope of Enablement) as set forth in the previous Office action dated February 26, 2010 at pages 2-5 as applied to claim 36 is hereby withdrawn because the applicants deleted the phrase, "prevention of Type II Diabetes".

Accordingly, the rejection made under 35 USC 102(b) as being anticipated by Bailly et al. (6,030,953) as set forth in the previous Office action dated February 26, 2010 at page 5 as applied to claims 1, 6, 8 and 9 is hereby withdrawn because the reference does not teach applicants' HIPE foam having a density of less than about 0.1 g/cc.

Accordingly, the rejection made under 35 USC 102(e) as being anticipated by Daggy et al. (6,607,749 B1 with prior filing date of September 8, 1999) as set forth in the previous Office action dated February 26, 2010 at pages 6-7 as applied to claims 1, 6, 8 and 9 is hereby withdrawn because the reference does not teach applicants' HIPE foam having a density of less than about 0.1 g/cc.

Accordingly, the rejection made under 35 USC 103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Niazi (6,251,421) as set forth in the previous Office action dated February 26, 2010 at pages 7-8 as applied to claims 23 and 25-27 is hereby withdrawn because the reference does not teach applicants' HIPE foam having a density of less than about 0.1 g/cc.

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Accordingly, the rejection made under 35 USC 103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Shiveley et al. (5,817,704) and further in view of Niazi (6,251,421) as set forth in the previous Office action dated February 26, 2010 at pages 8-10 as applied to claims 29-38 is hereby withdrawn because the reference does not teach applicants' HIPE foam having a density of less than about 0.1 g/cc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailly et al. (6,030,953) in view of Park et al. (5,750,585).

Bailly et al. teach a composition comprising chitosan (a HIPE foam) in combination with an inhibitor of gastrointestinal lapse (a lipase inhibitor), see the abstract. Note particular to column 4, lines 31-40 which teaches the instant composition can be formulated into tablets, suspensions and capsules. Also note the inhibitor of gastrointestinal lapse is orlistat (see column 5, lines 4-17).

The instant invention differs from the cited reference in that the cited reference does not teach the HIPE foam having a density of less than about 0.1 g/cc. However, the secondary reference, Park et al., teaches a non-digestible, non-absorbable, open-celled HIPE foam composition and method of orally administering said forms for the treatment of obesity. Note column 7, lines 35-46 teaches the density of the HIPE foam ranges from 0.015 to about 0.7 and more preferably range between 0.015 to 0.5 wherein the HIPE is more effective its absorbing properties. Note applicants' density range of less than about 0.1 g/cc falls within the cited reference optimal ranges.

Clearly, one skilled in the art would have assumed the preferred HIPE foam density of less than 0.1 g/cc is obvious since the preferred density size is old and well-known in the art.

Claims 1, 6, 8 and 9 are not allowed.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daggy et al. (6,607,749 B1 with priority filing date of September 8, 1999) in view of Park et al. (5, 750,585).

Daggy et al. teach a composition comprising methylcellulose (a HIPE foam) in combination with a lipstatin derivative (a lipase inhibitor), see the abstract. Note column 2, lines

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15-27 teaches the lipstatin derivative is tetrahydrolipostatin (orlistat). Also note column 17, claim 8 that the instant composition is compressed into a tablet.

The instant invention differs from the cited reference in that the cited reference does not teach the HIPE foam having a density of less than about 0.1 g/cc. However, the secondary reference, Park et al., teaches a non-digestible, non-absorbable, open-celled HIPE foam composition and method of orally administering said forms for the treatment of obesity. Note column 7, lines 35-46 teaches the density of the HIPE foam ranges from 0.015 to about 0.7 and more preferably range between 0.015 to 0.5 wherein the HIPE is more effective its absorbing properties. Note applicants' density range of less than about 0.1 g/cc falls within the cited reference optimal ranges.

Clearly, one skilled in the art would have assumed the preferred HIPE foam density of less than 0.1 g/cc is obvious since the preferred density size is old and well-known in the art.

Claims 1, 6, 8 and 9 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Park et al. (5, 750,585) and further in view of Niazi (6,251,421).

Bailly et al. and Daggy et al. were discussed above supra, individually, the combination of a HIPE foam polymeric material in combination with a lipase inhibitor. The secondary reference, Park et al, was cited to show that the applicants' HIPE foam density of less than about 0.1 g/cc is well-known in the art.

The instant invention differs from the cited references in that the cited references do not teach the instant composition is used in a kit. However, the tertiary reference, Niazi, teaches that compositions can be in the form of commercial packs containing a lipase inhibitor and instructions for its uses in the treatment of obesity or hyperlipidemia (see column 3, lines 39-44).

Claims 23 and 25-27 are not allowed.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Park et al. (5, 750,585) in view of Shiveley et al. (5,817,704) and further in view of Niazi (6,251,421).

Bailly et al. and Daggy et al. were discussed above supra, individually, the combination of a HIPE foam polymeric material in combination with a lipase inhibitor. The secondary

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reference, Park et al, was cited to show that the applicants' HIPE foam density of less than about 0.1 g/cc is well-known in the art.

The instant invention differs from the cited references in that the cited references do not teach the glass transition temperature from about -40°C to about 90°C to the said oral dosage forms. However, the tertiary reference, Shiveley et al., teaches that foams intended for applications requiring flexibility should contain at least in continuous regain having a T_g as low as possible is well-known in the art.

The instant invention differs from the cited references in that the cited references do not teach the instant composition is used in a kit. However, the fourth reference, Niazi, teaches that compositions can be in the form of commercial packs containing a lipase inhibitor and instructions for its uses in the treatment of obesity or hyperlipidemia (see column 3, lines 39-44).

Claims 29-38 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN WEDDINGTON
Primary Examiner
Art Unit 1614

/KEVIN WEDDINGTON/
Primary Examiner, Art Unit 1614

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